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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/060,022

01/28/2002

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forbes-pitchextr

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EXAMINER

BADIO, BARBARA P

ART UNIT

PAPER NUMBER

1612

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/060,022	<b>Applicant(s)</b> SONNIER ET AL.	
	<b>Examiner</b> Barbara P. Badio, Ph.D.	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.                                                |

**Nonfinal Office Action on the Merits**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Status of the Application***

2. Claims 1-19 are pending in the present application and are rejected as indicated below.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claim recites the limitation "wherein the mineral acid" in line 1. There is insufficient antecedent basis for this limitation in the claim. Parent claim 1 recites an "acid". Correction is requested.

5. Claim 19 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is

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required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

The instant claim recites the utilization of a solvent in step i) "selected from the group consisting of ketones and C1 to C8 hydrocarbons, or mixtures thereof". However, parent claim 1 recites a "solvent comprising at least one alcohol" and, thus, the solvent recited in claim 19 are not encompassed by claim 1.

***Claim Rejections - 35 USC § 102***

**6. The rejection of claim 20 under 35 USC 102(b) over Kutney et al. (US 5,770,749) is made moot by the cancellation of the instant claim.**

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. (WO 99/42471).

Wong et al. teaches a process for the preparation of phytosterols from tall oil pitch (see page 8, line 21 – page 9, line 18 of the present specification; see the entire article, especially page 3, line 22 – page 7, line 20) The process comprises (a)

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saponifying the sterol esters in the pitch to free phytosterol by the use of a water solution of an alkali metal base, such as sodium hydroxide, potassium hydroxide or a combination thereof at a temperature of 100 to 250°C for a period of 1 to 5 hours (see page 4, line 18 – page 5, line 22); (b) neutralizing the saponified pitch by the addition of sufficient acid, such as an organic acid, i.e., acetic acid or formic acid, or a mineral acid, i.e., sulphuric acid, hydrochloric acid or phosphoric acid, to reach a water pH between 4 and 7 (see page 5, line 23 - page 6, line 7); (c) maintaining the mixture at a temperature of 10 to 100°C for a period of 1 to 10 hours to effect the disengagement of water from the organic phase; (e) removing the excess water and heating the obtained organic phase to remove any additional water to form a modified pitch (see page 9, lines 9-18); (f) the modified pitch is introduced into an ultra-low pressure evaporator operating in the range of 0.1 to 10 millibars pressure and a temperature of 160 to 280°C for the removal of the light ends (see page 6, lines 19-23); (e) distilling the bottom fraction of the modified pitch containing the free phytosterols in a second ultra-low pressure wiped film evaporator operating at a pressure of 0.01 to 1.0 millibars pressure and a temperature of 180 to 300°C obtaining a light phase distillate (see page 7, line 24 – page 7, line 5); (f) dissolving said light phase distillate obtained in a solvent, such as monohydric alcohol, i.e., methanol, ethanol, 2-propanol or combination thereof (see page 7, lines 6-12); (g) cooling the mixture obtained to produce a slurry with phytosterols crystallized therein (see page 7, lines 13-16) and (h) washing and filtering to dryness the slurry (see page 7, lines 17-20). Wong teaches the use of wiped film evaporators and the recycling

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and reuse of the filtrate obtained after recovery of the pure phytosterol crystals (see Examples 2 and 4; page 7, lines 18-20).

The instant claims differ from the reference by reciting a preliminary distillation step of the tall oil pitch. However, the reference teaches a preliminary distillation of crude tall oil to obtain a depitched tall oil, containing fatty and rosin acids, and a tall oil pitch, containing a small amount of fatty and rosin acids and a substantial amount of the original unsaponifiables. Based on the level of skill of the ordinary artisan in the chemical art and the teaching of the art of the initial purification of the starting crude tall oil, further purification by distillation of the obtained tall oil pitch would be obvious. The motivation to further purify the starting material, i.e., tall oil pitch, is based on the desire to improve the purity the end product.

The claimed invention differ from the reference by reciting (a) an acid value of less than 30/40 (claims 2 and 3); (b) the occurrence of steps c) and d) in the same reaction vessel (claim 8); (d) vigorous agitation in step d) (claim 9); (c) step e) is carried out without agitation; (d) an additional phase separation of the water phase obtained after step e) and (e) the use of ketones, hydrocarbons or mixture thereof in step i).

The acid value of the starting material is dependent on the amount of acid, i.e., fatty and rosin acids, therein. Obtaining said acid value would require only routine experimentation which is well within the level of skill of the ordinary artisan. The motivation to obtain a lower acid value would be based on the desire to obtain a purer material for saponification.

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Performing an additional phase separation of the water phase is also prima facie obvious to the skilled artisan. The motivation would be the removal of any of the desired product that might be present in the water phase in order to increase the yield of the end product.

The art teaches various solvents/solvent systems for crystallization of sterols which is inclusive of alcohols, ketones, hydrocarbons or mixture thereof (see for example, US 7,371,876, col. 1, lines 46-50). Based on the level of skill of the ordinary art at the time of present invention, the utilization of a ketone or a hydrocarbon or a mixture thereof instead of an alcohol in the crystallization of the sterols as taught by Wong would have been prima facie obvious.

Lastly, the workup procedure(s), such as the use of different distillation columns or the use of the same vessel for multiple steps, is not a patentable distinction absence a showing of the criticality of said variation since said is well within the level of skill of the ordinary artisan in the art.

### ***Telephone Inquiry***

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Barbara P. Badio, Ph.D./  
Primary Examiner, Art Unit 1612